



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/633,204	07/30/2003	Shanta M. Modak	A33459-PCT-USA-A (070050)	3145
21003	7590	06/07/2006	EXAMINER CHOI, FRANK I	
BAKER & BOTT'S 30 ROCKEFELLER PLAZA 44TH FLOOR NEW YORK, NY 10112			ART UNIT	PAPER NUMBER 1616

DATE MAILED: 06/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/633,204	MODAK ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
 THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 7 October 2005, 22 March 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-4,7-16,19-31,33-37 and 39 is/are pending in the application.
 - 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-4,7-16,19-31,33-37 and 39 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date _____.
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: _____.

DETAILED ACTION

Priority

The benefit claim filed on 3/22/2006 was not entered because the required reference was not timely filed within the time period set forth in 37 CFR 1.78(a)(2) or (a)(5). Since the application is an application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii).

The preliminary amendment filed on 7/30/2003, the filing date of the Application herein, was not a proper claim for priority since the relationship, i.e. continuation, CIP, divisional, between the PCT application and the prior nonprovisional application, now US Pat. 6,582,719, was not set forth. See MPEP Section 201.11[R-3](C) and (D). Further, since the Patent Office did not recognize the claim for priority, if applicant desires the benefit under 35 U.S.C. 120 based upon a previously filed application, applicant must file a petition for an unintentionally delayed benefit claim under 37 CFR 1.78(a)(3) or (a)(6). Said petition must be accompanied by: (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted); (2) a surcharge under 37 CFR 1.17(t); and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Examiner contacted the Office of Petitions and was informed that the request, in the alternative, to consider the amendment filed on 3/22/2006 as a petition is not proper. A petition must be filed on a separate paper and sent to the address above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4,7-16, 19-31,33-37, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raad et al. (US Pat. 5,688,516) in view of Domenico et al. (Journal of Antimicrobial Chemotherapy (1991)), WO 97/25085 and Darouiche et al. (US Pat. 6,719,991).

Raad et al. disclose that chelating agents, such as zinc citrate and citrate and bismuth, inhibit the formation of glycocalyx produced by staphylcocci and Candida which glycocalyx helps said organisms adhere and stick to catheter surfaces (Column 1, lines 60-68, Column 2, lines 1-11, Column 4, lines 44,48,49,65,66). It is disclosed that a tetracycline antibiotic, such as minocycline which is effective in killing adherent staphylococci embedded in glycocalyx, is combined with said chelating agent and coated on the medical device (Column 6, lines 2-13, 40-50, claims 1,9,10,11,14-17). It is disclosed that the combination of tetracycline antibiotic and chelating agent can vary between about 0.001 to about 1,000 mg/ml, preferably between about 1 to about 200, or from 10 to about 100 mg/ml of the chelating agent (preferably between about 20 to about 100 or about 20 to about 60 mg/ml), and between about 0.001 to about 1000 mg/ml (preferable between about 10 to about 200 or from about 2 to about 100 mg/ml) and non-

glycopeptide antimicrobial agent (preferably between about 10 to about 100, or about 2 to about 9 mg/ml) (Column 6, lines 56-68). It is disclosed that in addition to said concentration ranges, other concentration ranges for use in coating a medical device include between about 10 mg/ml and about 200 mg/ml of the non-glycopeptide antimicrobial agent, such as minocycline, and between 10mg/ml and about 200 mg/ml of the chelating agent with one embodiment including 60 mg/ml of each (Column 8, lines 8-23).

Domenic et al. disclose that effects on growth inhibition of bacteria is due to the bismuth ion, salicylate ions have an additive effect when combined with bismuth, and that bismuth subsalicylate is effective in inhibiting capsular polysaccharide production by bacteria which forms bacterial biofilm (Pages 801,808). It is disclosed that the activity of salicylate against bacteria is due in part to chelation of cations required by polysaccharide synthetic enzymes (Pg. 801).

WO 97/25085 disclose treating polymeric medical articles, such as vascular catheters, with 1-5 % chlorhexidine, such as chlorhexidine free base, diacetate, digluconate, 0.5-5% triclosan, and that silver sulfadiazine (.5-1 %) can also be included (Page 4, lines 13-15, Pages 5, 6, Page 7, lines 1-12). It is disclosed additional anti-infective agents such as benzalkonium chloride can also be added (page 14, lines 3-9). It is disclosed that in specific embodiments the impregnating solution comprises between 0.1 and 10% anti-infective agent (Page 13, lines 18-24).

Darouiche et al. ('991) disclose the combination of an antibiotic, such as minocycline, and antiseptic, such as chlorhexidine, triclosan or silver, for coating catheters (Column 4, lines 6-27, column 7, lines 8-36, Column 8, lines 16-35, Column 10, lines 4-21). An "effective

concentration" is disclosed which is defined to mean that a sufficient amount of the antimicrobial agent is added to decrease, prevent or inhibit the growth of bacterial and/or fungal organisms; that will vary for each compound and upon known factors such as pharmaceutical characteristics, the type of medical device, use and length of use, etc.; and that it is within the skilled artisan's ability to relatively easily determine an effective concentration for each compound (Column 7, lines 49-57).

The prior art discloses the combination of chelating agents, such as zinc citrate and citrate and bismuth, with minocycline to prepare antimicrobial medical devices, such as catheters. The difference between the claimed invention and the prior art is that the prior art does not expressly disclose the combination of minocycline and chlorhexidine, the combination of minocycline, triclosan and bismuth, or minocycline and bismuth for treating a polymeric-containing medical articles. However, the prior art amply suggest the same as the prior art discloses that chlorhexidine, such as chlorhexidine digluconate, acetate or free base, can be combined with triclosan, silver sulfadiazine and benzalkonium chloride for preparing antimicrobial catheters; that bismuth ion inhibits bacterial growth, that bismuth subsalicylate is effective in inhibiting the formation of capsular polysaccharide by bacteria which forms bacterial biofilm, and that salicylate is a chelating agent; and that minocycline can be combined with triclosan, chlorhexidine or silver for preparation of antimicrobial catheters.

"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072

(CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie obvious*).).

See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960) (Claims directed to a method and material for treating cast iron using a mixture comprising calcium carbide and magnesium oxide were held unpatentable over prior art disclosures that the aforementioned components individually promote the formation of a nodular structure in cast iron.); and *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992) (mixture of two known herbicides held *prima facie obvious*). As such, it would have been well within the skill of one of ordinary skill in the art to modify the prior art as above with the expectation that the combination of minocycline and chlorhexidine, including gluconate, diacetate and/or free base, would be effective in preparing an antimicrobial catheter; and that the addition of bismuth, including bismuth salicylate or bismuth citrate, benzalkonium chloride, triclosan, silver and/or zinc would provided additional antimicrobial activity in the antimicrobial catheter.

Further, in view of the amount ranges disclosed above, the prior art discloses ranges of the above compounds that fall within, encompass or overlap the claimed ranges. In the case where the claimed ranges “overlap or lie inside ranges disclosed by the prior art” a *prima facie* case of obviousness exists. *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976); *In re Woodruff*, 919 F.2d 1575, 16 USPQ2d 1934 (Fed. Cir. 1990) (The prior art taught carbon monoxide concentrations of “about 1-5%” while the claim was limited to “more than 5%.” The court held that “about 1-5%” allowed for concentrations slightly above 5% thus the ranges overlapped.); *In re Geisler*, 116 F.3d 1465, 1469-71, 43 USPQ2d 1362, 1365-66 (Fed. Cir. 1997) (Claim reciting thickness of a protective layer as falling within a range of “50 to 100 Angstroms”

considered *prima facie* obvious in view of prior art reference teaching that “for suitable protection, the thickness of the protective layer should be not less than about 10 nm [i.e., 100 Angstroms].” The court stated that “by stating that suitable protection’ is provided if the protective layer is about’ 100 Angstroms thick, [the prior art reference] directly teaches the use of a thickness within [applicant’s] claimed range.”). Further, “[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955) (Claimed process which was performed at a temperature between 40°C and 80°C and an acid concentration between 25% and 70% was held to be *prima facie* obvious over a reference process which differed from the claims only in that the reference process was performed at a temperature of 100°C and an acid concentration of 10%); See In re Peterson, 315 F.3d 1325, 1330, 65 USPQ2d 1379, 1382 (Fed. Cir. 2003)(“The normal desire of scientists or artisans to improve upon that is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages.”)

Examiner has duly considered Applicant’s arguments but deems them unpersuasive.

Contrary to Applicant’s arguments, Raad et al. does provide teachings to indicate that the combination of a specific antiseptic agent combined with a specific tetracycline antibiotic will be effective in producing an anti-infective medical article. The amendment to the claims pursuant to a reissue does not provide any evidence that the combination of the same is not disclosed or suggested. Reissue claim 11 specifically contains combination of minocycline and bismuth and citrate which clearly relevant to claims of the present Application as bismuth ion is disclosed by Domenico et al. to inhibit bacterial growth. The fact that reissue claim 11 also requires an

anticoagulant or antithrombotic agent does not overcome the rejection herein as the claims of the present Application do not exclude the incorporation of other agents. In any case, the disclosure in Radd et al. clearly indicates that minocycline can be combined with chelating agents without the presence of anticoagulants or antithrombotic agents (See Radd et al., Column 4, lines 30-50). Further, contrary to Applicant's arguments, Radd et al. discloses teachings as to the concentration range of agents as indicated above.

Contrary to Applicant's arguments, as indicated above, the '991 patent discloses that the combination of an antibiotic, such as minocycline and antiseptic, such as chlorhexidine, triclosan or silver, is effective in providing antimicrobial activity to a medical device. The '991 patent does not expressly disclose the specific concentrations claimed in the present application; however, said patent discloses that the use of an "effective concentration" and that said concentration can be relatively easily determined by a skilled artisan. This is especially true in this case where the other prior art, as indicated above, discloses or suggests concentrations within, encompassing or overlapping that claimed in the present application.

With respect to WO 97/72085, Applicant argues that said reference at pages 5 and 6 merely discloses a long list of chlorhexidine derivatives or medical devices respectively. As indicated above, said medical devices are polymeric medical articles and include vascular catheters. Further, Applicant provides no evidence that one or more of the chlorhexidine derivatives, including those claimed in Applicant's dependent claims, exhibits unexpected activity over another. As such, since Applicant's claims are directed to polymer containing medical articles and chlorhexidine compounds, Applicant's arguments do not appear to overcome the rejection herein. Applicant argues that page 14, lines 3-9 of the reference does not

disclose dosages or effective combinations, however, as indicated above, the reference in combination with the other prior art does disclose or suggest both effective concentrations as well as effective combinations as claimed in the present application.

With respect to Domenico et al., although Domenico et al. does not expressly disclose the claimed concentration of bismuth subsalicylate, Domenico et al. must be viewed in combination with the other prior art, especially Raad et al.. Raad et al. discloses or suggest the claimed concentration of bismuth salt as indicated above. Raad et al. also discloses the use of chelating agents, such as bismuth and citrate. Domenico et al. discloses that bismuth subsalicylate has antibacterial activity and that the activity of salicylate against bacteria is due in part to its chelation of cations required by polysaccharide synthetic enzymes. As such, one of ordinary skill in the art would expect that bismuth subsalicylate would fall within the scope of chelating agents disclosed in Raad et al..

Applicant argues generally that the Specification provides several working examples that determine and demonstrate not only effective working combinations of an antiseptic and antibiotic but also that many combinations are ineffective under identical test conditions. However, the examples only appear to indicate that, at the concentrations or dosages used, that combinations of antimicrobial agents are generally better than use of the agents singly. It cannot be concluded that the examples show many combinations that are ineffective under identical test conditions. To the extent that some of the combinations exhibit inactivity at the concentrations or dosages used, said inactivity appeared to be only against one or two species of microbes (See Specification, Tables X-XII,XIV,XVII). The claims, however, are directed to anti-infective medical articles. In view of the teachings in the art that the combinations are antimicrobial, the

examples do not show that the combinations which showed inactivity against one or two species at the concentration or dosages used are not otherwise antimicrobial or would not provide anti-infective activity against at least one other species of bacteria or fungi. As such, since combinations of antimicrobials, including antibiotics and antiseptic agents, including the antibiotics and antiseptic agents claimed and concentrations thereof, are disclosed or suggested by the prior art to be effective antimicrobial agents in medical devices, such as vascular catheters, said examples are not sufficient to overcome the motivation to combine or modify the prior art herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4,7-16, 19-31,33-37, 39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of US Pat. 6,582,719 in view of Raad et al. (US Pat. 5,688,516), Domenico et al. (Journal of Antimicrobial Chemotherapy (1991)), WO 97/25085 and Darouiche et al. (US Pat. 6,719,991).

Claims 1-55 of US Pat. 6,106,505 claim an anti-infective medical articles, such as an intravenous catheter, which have been impregnated with a solution containing the combination of 1-5% chlorhexidine free base and 0.5-5% triclosan, which can further contain silver sulfadiazine (See claims 1-55).

Raad et al. (US Pat. 5,688,516), Domenico et al. (Journal of Antimicrobial Chemotherapy (1991)), WO 97/25085 and Darouiche et al. (US Pat. 6,719,991) are cited for the same reasons as above and are incorporated herein to avoid repetition.

US Pat. 6,106,505 claims anti-infective medical articles, such as intravascular catheters, which contain the combination of chlorhexidine and triclosan, which can further contain silver sulfadiazine. The difference between the claimed invention and the claims of US Pat 6,106,505 is that said US Patent does not expressly claim the combination of minocycline and chlorhexidine, the combination of minocycline, triclosan and bismuth, or the combination of minocycline and bismuth for coating medical devices, such as intravascular catheters. However, the prior art amply suggests the same as indicated above. As such, it would have been well within the skill of one of ordinary skill in the art to modify the claims of the '505 patent prior art as above with the expectation that the addition of minocycline or minocycline and bismuth, including bismuth salicylate or bismuth citrate, would increase the antimicrobial activity of the antimicrobial medical device. Examiner recognizes that independent claim 39 of the present

application does not recite either the use of chlorhexidine or triclosan. However, since it would be obvious to add minocycline and bismuth to claims of the '505 patent, said modification of the claims of the '505 patent would read on claim 39 of the present application. Further, it would have been well within the skill of one of ordinary skill in the art to use chlorhexidine gluconate, chlorhexidine free base and/or chlorhexidine diacetate in the claims of the '505 patent with the expectation that the same would be effective antiseptic agents for use in the medical devices and to add benzalkonium chloride or zinc citrate with the expectation that the same would increase the antimicrobial activity of the antimicrobial medical devices. Further, as indicated above, in view of the teachings of the prior art and the claims of the '505 patent, the claimed concentration ranges are *prima facie* obvious.

Examiner has duly considered Applicant's arguments but deems them unpersuasive. As indicated above, both the combination of the claimed antiseptics and antibiotics and concentrations thereof are disclosed or suggested by the prior art and claims of the '505 patent. As such, the obviousness double patenting rejection of claims 1-4, 7-16, 19-37, 39 over the claims of the '505 patent is maintained.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claims of US Pat. 6,106,505 to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of said claims and references.

Claims 1-4, 7-16, 19-31, 33-37, 39 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of US Pat. 6,582,719

in view of Raad et al. (US Pat. 5,688,516), Domenico et al. (Journal of Antimicrobial Chemotherapy (1991)) and WO 97/25085.

Claims 1-15 of US Pat. 6,582,719 claim an anti-infective medical article prepared by exposing a polymer-containing medical article with a solution containing 1-8% minocycline and 1-8% chlorhexidine free base or chlorhexidine diacetate, which can further contain 0.5-2% bismuth nitrate and/or 0.2-1.0% benzalkonium chloride; a solution containing said minocycline, 1-8% triclosan and said bismuth nitrate, which can further contain said benzalkonium chloride; a solution containing said minocycline and said bismuth nitrate; and intravascular catheters containing the combination of minocycline and chlorhexidine free base or chlorhexidine diacetate, which can further contain bismuth nitrate, benzalkonium chloride, silver sulfadiazine or silver carbonate; or the combination of minocycline, triclosan and bismuth nitrate, which can further contain benzalkonium chloride or silver carbonate (See claims 1-15).

Raad et al. (US Pat. 5,688,516), Domenico et al. (Journal of Antimicrobial Chemotherapy (1991)) and WO 97/25085 are cited for the same reasons as above and are incorporated herein to avoid repetition.

US Pat. 6,582,719 claims anti-infective medical articles, such as intravascular catheters, which contains the combination of minocycline and chlorhexidine; the combination of minocycline, triclosan and bismuth; and the combination of minocycline and bismuth. The difference between the claimed invention and the claims of US Pat 6,582,719 is that said US Patent does not expressly claim the use of bismuth citrate or bismuth salicylate, chlorhexidine gluconate or zinc salt. However, the prior art suggests the same as indicated above. As such, it would have been well within the skill of one of ordinary skill in the art to modify the claims of

the '719 to use bismuth citrate or bismuth salicylate in place of or in addition to bismuth nitrate with the expectation that the chelating activity of the salicylate or citrate would provide increased antibacterial activity, that zinc citrate would increase the antimicrobial activity of the antimicrobial medical device, and that to use chlorhexidine gluconate, chlorhexidine free base and/or chlorhexidine diacetate with the expectation that the same would be effective antiseptic agents for use in the medical devices. Further, as indicated above, in view of the teachings of the prior art and the claims of the '719, the claimed concentration ranges are *prima facie* obvious.

Examiner has duly considered Applicant's arguments but deems them unpersuasive. Examiner notes Applicant's statement that a terminal disclaimer will not be filed as to the '719 patent until allowable subject matter is indicated. As such, the obviousness double patenting rejection of claims 1-4, 7-16, 19-37, 39 over the claims of the '719 patent in view of the prior art is maintained.

Therefore, the claimed invention, as a whole, would have been an obvious modification of the claims of US Pat. 6,582,719 to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of said claims and references.

Conclusion

Examiner notes that US Pat. 5,624,704 has been removed from the rejections as being duplicative art relative to US Pat. 6,719,991 and that US Pat 6,719,991 has been removed from the obviousness double patenting rejection over the claims of the '719 patent as being duplicative prior art relative to the claims of the '719 patent. Further, although the listing of references has been altered and additional disclosure from said references has been cited in the rejections above to address Applicant's arguments, the rejections herein do not add additional references to make said rejections and the primary references remain primary references. As such, **THIS ACTION IS MADE FINAL**. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

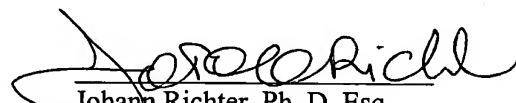
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
May 19, 2006



Johann Richter, Ph. D. Esq.
Supervisory Patent Examiner
Technology Center 1600